REMARKS

For the sake of clarity, claim 23 has been amended to recite a marker comprising a plurality of elongated strips composed of magnetostrictive amorphous metal alloy disposed in the marker's cavity with a non-parallel orientation. In addition, the obvious typographical error of the absence of a period to end claim 23 has been corrected.

In order to emphasize the patentable distinctions of applicant's invention over the prior art, claim 6 has been amended to call for a cavity included in the marker housing. The plurality of elongated strips of the magnetostrictive element are disposed in the cavity. Claim 23 has been amended to call for the housing to have one cavity in which a plurality of the magnetomechanical strips are disposed with a non-parallel orientation. Method claim 25 has been amended to call for use of a marker that includes a housing having a cavity therein, the strips of the magnetomechanical element being disposed in the cavity in a non-parallel orientation.

The foregoing amendment is clearly supported by the original specification; particularly at page 13, line 3 to page 14, line 10, and Figs. 2 and 3. Consequently, no new matter has been added by way of this amendment.

Claims 20-21 previously having been cancelled and claims 10 and 17 being withdrawn, claims 1-9, 11-16, 18-19, and 22-25 remain pending.

In the prior Office Action dated September 16, 2005, the Examiner objected to Figure 1, indicating that it apparently shows only that which is old. Accordingly, applicants' amendment dated December 19, 2005 included a replacement sheet bearing drawing Figures 1 and 2, wherein a legend characterizing Figure 1 as depicting prior art was added. The

present Office Action does not appear to contain any indication that the Examiner has withdrawn said objection, but applicants infer that the objection has properly been mooted. If any objection remains, the Examiner is kindly requested to make of record any further objection.

Applicants' invention, as delineated by pending claims 1-9, 11-16, 18-19, and 22-24, is directed to a surgical implement detection system for detecting surgical implements within a wound at the conclusion of a surgical procedure. Compared to previously-known markers for article detection systems, the present inventive marker has a significantly reduced size, facilitating its attachment or similar association with surgical implements, including both reusable surgical tools, disposable items such as surgical sponges, or other like articles.

The problem of implements left behind after the completion of surgical procedures remains a serious and vexing medical issue, because if undetected, these items are highly likely to cause serious, and possibly fatal, injury to a patient. The present system provides a procedure whereby these items can be reliably, quickly, and efficiently detected in the harried and intense environment of an operating room, even prior to the completion of the surgical procedure and closure of the surgical wound, thereby avoiding the risk of infection and other injury to the patient, and obviating the need for further invasive, deleterious, and painful follow up care otherwise inexorably required.

The Examiner has rejected claim 23 under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter regarded as the invention. In particular, it is said that the term "said strips" in line 2 is indefinite, because base claim 22 recites "one or more elongated strips." Applicants respectfully submit that the recitation of the non-parallel orientation of the strips in claim 23, read in

light of the teaching of the specification, e.g. at page 13, line 3 to page 14, line 10 (describing Figs. 2 and 3), clearly establishes that more than one strip is contemplated. Nevertheless, for the sake of clarity, claim 23 has been amended to call for a plurality of strips, thereby obviating any possible indefiniteness. It is thus submitted that the statutory requirement of 35 USC 112, second paragraph, is now satisfied by claim 23, in that the subject matter regarded by applicants as the invention has been particularly pointed out and distinctly claimed.

Accordingly, reconsideration of the rejection of claim 23 under 35 USC 112, second paragraph, as being indefinite is respectfully requested.

The Examiner has rejected claims 1-5, 14-16, 18, 19, and 22 under 35 USC 102(b) as being anticipated by US Patent No. 5,057,095 to Fabian, which discloses a surgical implement detector utilizing a resonant marker. In one embodiment, the marker is magnetomechanical.

With respect to claims 1, 2, 14, and 22, the Examiner has indicated that Fabian teaches a magnetomechanical marker having a resonant frequency in the range of 0-1 GHz, which is said to include the 70-300 kHz range delineated by claims 1, 2, 14, and 22. Applicant respectfully observes that the cited teaching in fact discloses the range of "below about 1 gigahertz" (col. 4, line 1), but delineates three distinct types of resonance, i.e. magnetomechanical, electromechanical, and electromagnetic. Nothing in the Fabian reference specifically associates a 0-1 GHz range with a magnetomechanical marker. Clearly there is no disclosure of the particular 70-300 kHz range delineated by claims 1, 2, 14, and 22, and there are no species of magnetomechanical marker disclosed for which any particular numerical value of frequency is recited, let alone any species operative within the

70-300 kHz range. To the contrary, the only disclosure in Fabian of a particular species pertinent to a magnetomechanical marker is at col. 8, lines 6-23, in which testing was carried out using a "conventional magnetomechanical system." Applicant respectfully maintains that one having ordinary skill in the art would recognize that conventional magnetomechanical systems would operate at much lower frequencies than the claimed 70-300 kHz range, with 58 kHz being a typical operating frequency at which the marker is resonant. Accordingly, it is submitted that any disclosure of Fabian falls far short of rebutting the novelty of the subject matter of claims 1, 2, 14, and 22.

Furthermore, it is submitted that one of ordinary skill in the art would immediately recognize that it would be impossible to construct a magnetomechanical marker having a resonant frequency of 1 GHz. Such a frequency is a factor of over 17,000 times larger than the 58 kHz of a typical magnetomechanical marker. Therefore, the resonant element of a 1 GHz marker would have to be 17,000 times shorter than the 1.5" length of the resonant element in a typical 58 kHz marker, and would be clearly impossible to construct, and would have such a miniscule volume as to produce an undetectably small signal, even if it could be constructed.

Applicant further submits that nothing in the Fabian reference would suggest a magnetomechanical marker wherein the resonant element has a resonant frequency in the range of about 70 to 300 kHz. As set forth at page 8, line 19 to page 9, line 3; page 18, lines 1-15; and page 18, line 23 to page 19, line 10, a marker constructed to operate within such a frequency range advantageously is smaller in size than conventional magnetomechanical markers used in connection with a surgical implement, such as that disclosed by Fabian, but nevertheless has an adequate volume of magnetic material to emit a signal that is large enough to permit highly reliable, rapid detection of the marker in the adverse environment of

surgery. Clearly, speed and reliability of detection are of paramount importance in such a situation. In addition, the compact size permits surgical items to be tagged that would be physically impossible to tag using larger conventional markers.

Therefore, applicants respectfully maintain that Fabian falls far short of the specificity of disclosure that would be required to properly ground a *prima facie* anticipation of claims 1-5, 14-16, 18, 19, and 22. Absent disclosure that every feature recited by a claim is disclosed by a single reference, either explicitly or implicitly, such a rejection is impermissible, as the Federal Circuit has repeatedly held. See, e.g., in the context of chemical arts, *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 51 USPQ2d 1943 (Fed. Cir. 1999). ["To anticipate a patent claim, a prior art reference must disclose every limitation of the claimed invention, either explicitly or inherently...When a patent claims a chemical composition in terms of ranges of elements, any single prior art reference that falls within each of the ranges anticipates the claim; a single prior art species within the patent's claimed genus reads on the generic claim and anticipates. *Id.* at 1346.]

It is established law that a reference that describes subject matter delineated by a numerical range of composition does not *per se* anticipate a claim delineating a different range merely because of the overlap of such ranges. While the numerical range recited in the present instance by claims 1, 2, 14, and 22 admittedly is a frequency range, not a chemical composition range, applicants nevertheless maintain that the recited range clearly defines the structure of the marker, so that the same law is apposite. While the existence of a prior art species falling within a claimed generic range has been held to anticipate the claimed genus, in the present instance no species of Fabian has been identified that falls within the claimed ranges. Absent such an identified species, a case-specific factual analysis is required to establish possible anticipation. *Ex parte Cole*, 2001 WL 1918535

(BPAI, 2001), quoting *Ex parte Lee*, 31 USPQ2d 1105, 1107 (BPAI, 1993). Explaining the nature of the factual analysis, the Board of Patent Appeals and Interferences required a determination of the specificity of disclosure. ["Where, as here, a reference describes a class of compositions, the reference must be analyzed to determine whether it describes a composition(s) with sufficient specificity to constitute an anticipation under the statute. *Ex parte Lee*, supra, at 1106-1107, emphasis added, citing *In re Schaumann*, 572 F.2d 312, 197 USPQ 5 (CCPA 1978).]

The Federal Circuit has recently applied similar reasoning in regard to the question of process parameter limitations, holding that a prior art disclosure of a process temperature range of 100-500°C did not anticipate a claim limitation of 330 to 450°C. ["Given the considerable difference between the claimed range and the range in the prior art, no reasonable fact finder could conclude that the prior art describes the claimed range with sufficient specificity to anticipate this limitation of the claim." *Atofina v. Great Lakes Chemical Corp.*, 441 F.3d 991, 2006 U.S. App. LEXIS 7180, slip op. at 22 (Fed. Cir. 2006)]. Applicant respectfully submits that the law established by the *Atofina* court is apposite the facts of the present instance. That is to say, the *Atofina* court's holding that mere disclosure of a temperature range overlapping a claimed temperature range is not anticipatory is also applicable to applicant's claimed resonant frequency range, which at best falls within a much wider disclosed range. Applicants respectfully submit that the same reasoning that led the *Atofina* court to distinguish a prior art 100-500°C temperature range from a claimed 330 to 450°C range applies with equal force to the distinction between the 0-1 GHz range disclosed by Fabian and the present claimed 70 – 300 kHz range. Applicants respectfully submit that the Examiner's analysis fails to establish the present limits with the "sufficient specificity" required under *Lee* and *Atofina* to sustain an anticipation rejection. Clearly,

even accepting *arguendo* the Examiner's contentions regarding 50 and 445 kHz set forth on page 9 of the present Office Action, no evidence has been adduced, let alone any species falling within the claimed 70-300 kHz, which could purport to provide that specificity. Applicants thus maintain that *prima facie* novelty has not been established.

In the present instance, the Examiner has alleged anticipation by Fabian. Applicants respectfully disagree. Clearly, the particular range limitations of applicants' claims 1, 2, 14, and 22 ("from about 70 to 300 kHz") are nowhere to be found in Fabian. Even less is there disclosure or suggestion of the preferred ranges of claims 12 and 13. Moreover, the Examiner's analysis does not address any teaching in Fabian indicating that one would know the claimed ranges, and thereby rise to the level of specificity required to constitute anticipation under *Lee*. The Examiner has merely made the undisputed and unremarkable observation that a 70-300 kHz range numerically falls within the vastly broader and alleged 0-1 GHz range.

Applicants thus maintain that Fabian fails to disclose every feature delineated by independent claims 1, 2, 14, and 22. Even less does Fabian disclose every feature of dependent claims 2-5, 15-16, 18, and 19, as amended which are submitted to be novel for at least the same reasons as claims 1, 2, 14, and 22.

Moreover, applicants submit that nothing in Fabian would lead a skilled artisan to the particular frequency range required by applicants' claims. Such a range surprisingly and unexpectedly permits the present magnetomechanical technology to be extended to a far wider range of surgical implements than would be possible using the much larger prior-art tags needed for operation at conventional magnetomechanical frequencies. Such lack of disclosure even further rebuts any purported conclusion that Fabian provides the requisite

level of specificity of disclosure. ["If the claims are directed to a narrow range, the reference teaches a broad range, and there is evidence of unexpected results within the claimed narrow range, depending on the other facts of the case, it may be reasonable to conclude that the narrow range is not disclosed with 'sufficient specificity' to constitute an anticipation of the claims. The unexpected results may also render the claims unobvious." MPEP 2131.03 (II).]

In response to applicants' arguments concerning the lack of specific disclosure of resonant frequency, the Examiner has pointed to How et al., Tanji et al., Hasegawa et al., and VonHoene et al. as allegedly corroborating the Examiner's position that the magnetomechanical resonator operates in at least a frequency range of 50 to 445 kHz.

Applicants respectfully submit that the citation of the How et al., Tanji et al., Hasegawa et al., and VonHoene et al. references in an anticipation rejection is improper. Clearly, the citation does not satisfy any of the narrow situations set forth in MPEP 2131.01 in which multiple references are properly employed in a rejection under 35 USC 102. Of the three circumstances therein enumerated, circumstances A ("prove the primary reference contains an 'enabled disclosure') and B ("explain the meaning of a term") are not pertinent. Applicants also maintain that circumstance C ("show that a characteristic not disclosed is inherent") is not satisfied. The Examiner's own statement of his position "that the mechanical resonator of Fabian operates in at least a frequency range of 50-445 kHz," purportedly established by appeal to the How et al., Tanji et al., Hasegawa et al., and VonHoene et al. references, falls far short of establishing that any magnetomechanical marker disclosed by Fabian operates in the claimed 70 – 300 kHz range. At the very best, the cited references might be argued to establish overlapping ranges, but the required specificity under *Lee* and *Atofina* is still lacking.

In view of the foregoing remarks, it is submitted that the system of claims 1-5, the method of claims 14-16 and 18-19, and the implement of claim 22 are novel over Fabian.

Accordingly, reconsideration of the rejection of claims 1-5, 14-16, 18-19, and 22 under 35 USC 102(b) as being anticipated by Fabian is respectfully requested.

Claims 6-8, 23, and 25 were rejected under 35 USC 103(a) as being unpatentable over Fabian in view of US Patent Publication No. 2002/0005783 to Irrizary et al., which provides a child monitoring device.

The Examiner has acknowledged that Fabian fails to disclose a marker wherein the magnetomechanical element comprises a plurality of elongated strips, as required by claims 6-8, 23, and 25, but has cited Irrizary et al. as allegedly disclosing such a structure, e.g. at paragraph [0034]. Applicant respectfully submits that the tag of Irrizary et al. comprises two magnetomechanical markers, having elongated axes that are perpendicular. Whereas each of the mechanical markers (e.g. markers 25 and 26 of tag 21 shown in Fig. 2) of Irrizary et al. separately includes a magnetomechanical elongated strip, applicant's marker includes a magnetomechanical element comprising a plurality of elongated strips. As set forth by claim 4, feature (c), on which claim 6 depends, a housing encloses the magnetomechanical element and the bias means. Furthermore, claim 6 is presently amended to expressly recite that the housing includes a cavity in which the plurality of elongated strips are disposed. Claim 23 is similarly amended to recite a marker including one cavity and a plurality of strips disposed in that cavity. Claim 25 is now amended to call for the marker to have a housing and a cavity therein and a plurality of elongated strips disposed in the cavity in a non-parallel orientation. Therefore, it is respectfully submitted Irrizary et al. does not disclose a marker wherein a magnetomechanical element comprises plural strips

that together constitute a magnetomechanical element and are together enclosed in a housing. Rather, the Irrizary et al. marker comprises multiple magnetomechanical elements that are enclosed in cavities in separate housings, even if the multiple markers are mechanically joined. Irizarry et al. further fails to disclose or suggest the particular resonant frequency range delineated by applicants, thereby failing to cure the aforementioned deficiency of Fabian, even if the references are taken in combination.

With respect to claim 23, the Examiner has pointed to paragraph [0034] of Irizarry et al. as allegedly motivating the inclusion of a second non-parallel strip. However, the Irizarry et al. marker is inherently more complicated and harder to construct, and also requires plural bias means, as a result of the use of separate cavities in which the plural magnetostrictive elements are disposed. It is respectfully submitted that the Examiner has not provided any motivation for the substantial reconstruction of the Irizarry et al. marker that would be required to reach applicants' claimed subject matter.

It is thus respectfully submitted that even in combination, Fabian and Irrizary et al. do not disclose or suggest the system delineated by applicant's claims 6-8, the surgical implement of claim 23, and the method of claim 25, as amended.

Accordingly, reconsideration of the rejection of claims 6-8, 23, and 25 under 35 USC 103(a) as being unpatentable over Fabian in view of Irrizary et al. is respectfully requested.

Claims 9, 11-13, and 24 were rejected under 35 USC 103(a) as being unpatentable over Fabian in view of Irrizary et al. and further in view of US Patent 6,359,563 to Herzer and US Patent 6,407,676 to Tanji et al.

Herzer provides a magneto-acoustic marker for electronic article surveillance having reduced size and high signal amplitude. Tanji et al. provides a magnetostrictive resonator

appointed to be embedded in a roadway for use in connection with a vehicle detection system.

The Examiner has acknowledged that the combination of Fabian and Irrizary et al. fails to disclose a configuration having first and second magnetomechanical strips on either side of a bias magnet, but contends that Herzer teaches use of a plurality of resonator pieces to allow the width of the marker to be reduced and that Tanji et al. teaches placing resonators on both sides of the bias magnet to allow the marker to be made smaller.

However, applicant respectfully submits that even in combination, Fabian, Irrizary et al., Herzer, and Tanji et al. fail to teach the claimed frequency range of about 70 to 300 kHz, as delineated by claims 1, 2, 14, and 22, on which claims 9, 11-13, and 24 depend. Accordingly, it is submitted that claims 9, 11-13, and 24 are patentable for at least the same reasons as claims 1, 2, 14, and 22, as set forth hereinabove.

Accordingly, reconsideration of the rejection of claims 9, 11-13, 21, and 24 under 35 USC 103(a) as being unpatentable over Fabian in view of Irrizary et al. and further in view of Herzer and Tanji et al. is respectfully requested.

CONCLUSION

In view of the amendments to claims 6, 23, and 25 and the foregoing remarks, it is respectfully submitted that the present application has been placed in allowable condition. Reconsideration of the Final Rejection, entry of the present amendment, and allowance of claims 1-9, 11-16, and 18-25 are, therefore, earnestly solicited.

Respectfully submitted,

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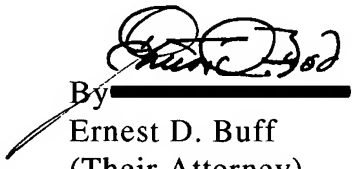

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